

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
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THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9459

Bartle, J.

March 1, 2016

The Estate of Dennis J. Kennedy ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Patti Kennedy ("Ms. Kennedy"), the spouse of Dennis J. Kennedy ("Mr. Kennedy"), also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of

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To seek Matrix Benefits, a representative claimant⁴ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In June, 2013, Ms. Kennedy, the personal representative of the Estate, submitted a completed Green Form to the Trust

3. (...continued)

their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

signed by the attesting physician, Robert L. Rosenthal, M.D.⁵ Based on an echocardiogram dated February 7, 2002, Dr. Rosenthal attested in Part II of the Green Form that Mr. Kennedy suffered from mild aortic regurgitation, had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™, and suffered ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.⁶ Based on such findings, the Estate would be entitled to Matrix A-1, Level V⁷ benefits in the amount of \$1,240,196.⁸

5. The Estate previously submitted a claim for Level III benefits in December 2011. This Court affirmed the Trust's determination that the Estate was entitled to Matrix B, Level III benefits. See Pretrial Order ("PTO") No. 9226 (Apr. 15, 2014). The Third Circuit affirmed this Court's decision following the Estate's appeal. See In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 601 F. App'x 162 (3d Cir. 2015).

6. Dr. Rosenthal also attested that Mr. Kennedy had New York Heart Association Functional Class I Symptoms. This condition is not at issue in this claim.

7. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the Diet Drug Recipient qualifies for Level III Matrix Benefits and suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A representative claimant is entitled to Level III benefits if the Diet Drug Recipient suffered from "left sided valvular heart disease requiring . . . [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Id. § IV.B.2.c.(3)(a).

8. The Estate previously received Matrix B-1, Level III benefits in the amount of \$171,921. According to the Trust, if entitled to Matrix A-1, Level V benefits, the Estate would be entitled to Matrix Benefits in the amount of \$1,412,117. The amount at

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Dr. Rosenthal also attested in the Green Form that Mr. Kennedy did not suffer from congenital aortic valve abnormalities. Under the Settlement Agreement, the presence of congenital aortic valve abnormalities, specifically, "unicuspid, bicuspid or quadricuspid aortic valve[s], [or] ventricular septal defect associated with aortic regurgitation," requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)a). As the Trust does not contest the Estate's entitlement to Level V benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A or Matrix B.

In August, 2013, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for Dr. Rosenthal's representation that Mr. Kennedy did not have a congenital aortic valve abnormality:

There was evidence of bicuspid valve
(Pathology and [transesophageal echocardiogram] 3/28/07).

Intraoperative [transesophageal echocardiogram] showed bicuspid aortic valve

8. (...continued)
issue, therefore, is the difference between the Matrix B-1, Level III benefits already paid and the amount of Matrix A-1, Level V benefits. See Settlement Agreement § IV.C.3.

which was confirmed by pathological findings.⁹

Based on Dr. Wang's finding that Mr. Kennedy had a congenital aortic valve abnormality, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.¹⁰ In contest, the Estate argued that the Trust improperly ignored the operative report for Mr. Kennedy's aortic valve surgery. That report stated that Mr. Kennedy's aortic valve was trileaflet. The Estate's position was that the report should have been considered because the Green Form permits a finding of a congenital bicuspid aortic valve to be based on a review of an echocardiogram, a cardiac catheterization, or a surgical examination. In addition, the Estate argued that the auditing cardiologist did not make a

9. Dr. Wang also determined that there was no reasonable medical basis for Dr. Rosenthal's finding that Mr. Kennedy did not have aortic stenosis as defined by the Settlement Agreement. Under the Settlement Agreement, the presence of aortic stenosis also requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). Given our disposition with respect to Mr. Kennedy's congenital aortic valve abnormality, we need not address this issue.

10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

definitive finding that Mr. Kennedy's bicuspid aortic valve was congenital.

The Estate also submitted declarations from Manoj R. Muttreja, M.D., and Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C. In his declaration, Dr. Muttreja stated, in pertinent part:

3. At time 0.25 on the 2/7/02 study, it was previously alleged that the aortic leaflets (cusps) did not close in the midline. There was no evidence of this. In fact, an unbiased cardiologist could not see the leaflets close in this view, due to the picture quality. However, the [aortic insufficiency] jet indicated that the leaflets closed in the midline. The [aortic insufficiency] jet in this case was very central. In contrast, if the leaflets did not close in the midline as previously claimed, the [aortic insufficiency] jet would be very eccentric. The presence of a central jet and the absence of a eccentric jet showed that the cusps closed in the midline, which would indicate that the patient did not have a congenital bicuspid aortic valve.

4. Also, the conditions found at time 2:59 were **not** diagnostic of a congenital bicuspid valve. In real time, it appeared that the valve had three leaflets. Further, in real time at around the 3:53 mark, the calcification stretched from annulus edge to annulus edge, across the upper third of the aortic valve. Calcification in the case of a congenital bicuspid valve would not transverse across the annulus in this manner. Instead, in the case of a congenital bicuspid valve, the calcification would arise from the annulus and extend to the midline, thus fusing the right coronary cusp (RCC) and the left coronary cusp (LCC). This complete fusion of the RCC and LLC is known as a raphe. . . . However, the calcification pattern in this case was consistent with focal calcification of the RCC, and such

pattern was inconsistent with a congenital bicuspid valve. Indeed, an aortic valve need not to be bicuspid to calcify. A normal tricuspid valve will undergo calcification, as in the instant case. See Exhibit C, which shows nodules of calcification on the aortic valve cusps.

5. With regard to the 3/5/07 study, it was previously alleged that the aortic valve did not close in the midline, and that there was obvious congenital fusion of the RCC and the LCC. The echocardiogram images found on the 3/5/07 study were far worse than the images found on the 2/7/02 study, and again there was no evidence that the aortic valve did not close in the midline. Further, the calcification pattern seen on the 3/5/07 study was the same pattern seen on the 2/7/02 study. This calcification pattern once again established that there was no congenital fusion of the RCC and the LCC.

6. With regard to the 3/28/07 [transesophageal echocardiogram], there was no congenital fusion of the RCC and the LCC, with a raphe between these two cusps. There was no raphe shown on the 3/28/07 [transesophageal echocardiogram], or any other echocardiographic study. As shown . . . a raphe is a complete fusion that goes to the midline of the valve. In a true congenital bicuspid valve, the raphe is often the most calcified portion of the valve. As set forth in paragraph 3 above, a central [aortic insufficiency] jet on the 2/7/02 echocardiogram indicated that the valve opened at the midline (i.e.-it was not fused at the midline). Further, the calcification pattern clearly seen on the 3/28/07 [transesophageal echocardiogram] once again established that the aortic valve was not congenitally bicuspid. The most prominent calcium was seen along the entire leading edge of the noncoronary cusp (NCC). Other significant calcification was found at the commissure of the RCC near the annulus on the NCC side and at the midportion of the LCC, on

the RCC side. The calcification pattern was very irregular, which is inconsistent with the presence of a congenital bicuspid valve.

7. Indeed, calcification between the RCC and the LCC was very minor. This finding indicated that there was a partial acquired fusion of the RCC and the LCC, but there was no full fusion on these cusps, as in the case of a congenital bicuspid valve. Further, on account of the full fusion of the RCC and the LCC in the case of the congenital raphe, these cusps do not separate. As a result of the full fusion, the two cusps move together. Thus, a congenital bicuspid valve opens and closes with an orifice that resembles a fish mouth or oval. . . . This was clearly not the patient's case. In his case, the RCC and the LCC did not move together. Instead, the RCC and LCC separated. The LCC moved and the RCC did not. Thus, the cusps formed a tripartite "Mercedes Benz" sign, which is diagnostic of a tricuspid aortic valve. . . .

8. On the 3/28/07 [transesophageal echocardiogram], real time loops 10, 11, 12, 13, 28, 29, 30, and 43 did not show a congenital bicuspid valve. I agree that it is important to look at the cusps in real time, rather than in isolation. With regard to specific times and a view in real time, I found a definite tricuspid aortic valve in the short axis aortic view at times 9:12:13 to 9:12:14, 9:12:23 to 9:12:24, and 9:18:33 to 9:18:35. As set forth above, in real time, I found that the valve opening was not like a fish mouth, which is classic for a congenital bicuspid valve. Instead, the opening was in the form of an eccentric boomerang shape, which is consistent with a partially fused commissure in a trileaflet valve that developed calcific aortic stenosis.

9. Further, a congenital bicuspid valve was not "confirmed" by the pathologist. In his findings, the pathologist did not mention a bicuspid valve. Objectively, the pathologist

described what he saw, which was a large fragment that "...appears fused with a possible central raphe." Clearly, the diagnosis of a bicuspid valve from a pathologic specimen is very difficult. The pathologist receives the valve in pieces that are removed from the human body at the time of surgery, and oftentimes, the pieces cannot be fully put together as a puzzle.

10. In contrast to the pieces of the valve that were seen by the pathologist, the echocardiographer and surgeon observed an intact aortic valve at the time of surgery. The surgeon stated that he saw a trileaflet valve that was heavily calcified. The echocardiographer mentioned a fusion of the left and right coronary cusps, but he did not state that the valve was bicuspid. In fact, the echocardiographer described the valve just as I have described it, and these descriptions are consistent with a tricuspid valve. Clearly, both the surgeon and the echocardiographer are experienced physicians, who would have made a diagnosis of a bicuspid valve if that were the case.

11. In the operating rooms, I have observed over 1000 cases in which the RCCs and the LCCs were partially fused due to calcifications that occurred later in the patients' lives. These were not congenital bicuspid valves. Rather, the valves remained trileaflet, as directly observed by the surgeon in this case.

12. In conclusion, it is unreasonable to conclude that the patient had a congenital bicuspid aortic valve. Instead, the evidence clearly shows that the valve was tricuspid.

In his declaration, Dr. Dlabal stated, in relevant part:

3. A review of the 3/28/07 [transesophageal echocardiogram] revealed no evidence of a congenital bicuspid valve. A normal aortic valve (AoV), in cross-sectional views, has

three cusps which meet in the middle, such that the lines of apposition form a "Mercedes Benz" sign, readily seen on echocardiogram. In this case, image loops 28, 29 (and to a less quality 39) are cross-sections of the AoV. These cross-sectional views clearly show the presence of three cusps, therefore no congenital deformity was found. There was no fusion (raphe) between the right coronary cusp (RCC) and the left coronary cusp (LCC). The cusps were thickened and two might have been partially fused, thus rendering the appearance of a "bicuspid" valve. . . . However, on closure they produced the tri-partite "Mercedes Benz" sign, which confirms the presence of a congenitally normal tricuspid (trileaflet) AOV.

4. A re-review of the 2/7/02 echocardiogram showed a deformed, but tri-partite AoV, with thickening between the RCC and non-coronary cusp (NCC), but no clear evidence of a Bicuspid AoV. (Poor echo quality, still difficult to tell, but that is what I saw.) Further, the [aortic insufficiency] jet was central; that would not happen if the valve were naturally bicuspid. It would be eccentric. Further, since there was no evidence of a bicuspid valve in 2007, this condition could not have been present in 2002.

5. The surgeon reported the valve to be tricuspid. The surgeon has the BEST view of anatomy. A cardiologist cannot do better than seeing the valve *in vivo*, with all attachments in place.

6. The pathologist report was internally contradictory. He received two leaflets, but noted that there was a fused raphe in one leaflet, therefore (by definition) rendering the valve tricuspid (trileaflet) by nature, and by definition.

7. Most patients with a bicuspid valve also have Left-Dominant circulation. This patient did not; his coronaries were Right-Dominant.

8. Most patients receiving medical care in the US, sports physicals, etc. will be diagnosed with a bicuspid valve in childhood or adolescence. This patient was not; therefore it was unlikely that he had a bicuspid valve on this basis.

9. Clearly, on the basis of the evidence, this patient did not have a congenital bicuspid valve. Instead, there was a partial fusion of two (out of three) leaflets, thus rendering the valve "functionally" bicuspid. A normal aortic valve has three leaflets, and two of those leaflets may later become partially fused, as in this case. However, when three leaflets have been identified, such partial fusion is not the congenital absence of a leaflet. In other words, the functionally bicuspid valve found in this case was not the same as an anatomically congenital bicuspid valve.¹¹

Accordingly, the Estate asserted that it was entitled to Matrix A benefits.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Wang submitted a declaration in which she again concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have a congenital aortic valve abnormality. Dr. Wang stated, in pertinent part:

11. The Estate also incorporated, by reference, its previous contest materials for the Estate's Level IIII claim. The Estate's reliance on these materials is unpersuasive, as the Court, and the Third Circuit, already have determined that these materials were insufficient to establish a reasonable medical basis for a finding that Mr. Kennedy did not have a congenital bicuspid aortic valve.

11. With respect to congenital aortic valve abnormalities, I confirm that Claimant had a bicuspid aortic valve. Bicuspid aortic valves may assume three different types of configuration: (1) "Real" bicuspid valves with two symmetric leaflets; (2) tricuspid architecture with a fusion of two leaflets, or (3) tricuspid architecture with a fusion of three leaflets. Claimant has the second type of bicuspid aortic valve - tricuspid architecture with a fusion of two leaflets, and with calcification on the raphe. Calcification would not cause fusion of the two leaflets. As reported on the pathology report, Claimant's aortic valve consisted of two aortic valve cusps, the largest fragment appearing fused with a possible central raphe. The classic congenital bicuspid aortic valve - fusion of left and right cusps - was also demonstrated in the [transesophageal echocardiogram] on March 28, 2007. Patients with bicuspid valve tend to develop aortic stenosis at a young age, typically between the ages of 45 and 65, while those with tricuspid aortic valve develop degenerative aortic stenosis from 70 to 85. Claimant was 52 years old at the time of aortic replacement, which is more supportive of bicuspid aortic valve. For all these reasons, I conclude that claimant had congenital aortic valve abnormalities, in the form of a congenital bicuspid aortic valve. There is no reasonable medical basis to conclude otherwise.

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why this claim should be paid. On June 29, 2015, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9423 (June 29, 2015).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on September 3, 2015, and the Estate submitted a sur-reply on September 18, 2015. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹² to review claims after the Trust and the representative claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge[-]helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have a congenital aortic valve abnormality. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate reasserts the arguments made in contest. The Estate also argues that it satisfied the reasonable medical basis standard required by the Settlement Agreement. Further, the Estate contends that, in finding a congenital bicuspid aortic valve, the auditing cardiologist ignored Mr. Kennedy's echocardiogram reports, his March 6, 2007 heart catheterization, and the surgery report for his aortic valve surgery. The Estate also maintains that Dr. Wang improperly "relied on a single sentence contained in the 'Final Diagnosis' found at the top of the Pathology Report" that it argues is "internally inconsistent." In addition, the Estate

again challenged the report of the Technical Advisor issued in connection with the Estate's Level III claim. Finally, the Estate submitted a supplemental declaration from Dr. Muttreja, who stated, in pertinent part:

3. In her declaration, Dr. Wang concedes that Claimant did not have a "real" bicuspid valve. A "real" bicuspid valve is a congenital bicuspid valve, and for reasons stated in my December 11, 2013 declaration, Claimant did not have a "real" (or congenital) bicuspid valve. Further, Dr. Wang claimed that the aortic valve had a "tricuspid architecture," with fusion of two leaflets and with calcification on the raphe. However, as I explained in my prior declaration, the right coronary cusp (RCC) and the left coronary cusp (LCC) were only partially fused due to a very minor amount of calcification between these two cusps. There was no congenital fusion of these cusps, and there was no raphe.

4. Dr. Wang also stated that, "Calcification would not cause fusion of the two leaflets." This statement is also incorrect. Ultimately, this patient developed aortic stenosis. The progression of this disease involved a pathologic process that caused calcification of the leaflets, the commissures, and the annulus. The calcification caused a partial fusion of the RCC and LCC, which was followed by aortic valve stenosis.

5. Additionally, Dr. Wang claimed that aortic stenosis at age 52 was "more supportive" of a bicuspid aortic valve. Clearly aortic stenosis at age 52 does not indicate a congenital bicuspid valve. Valvulopathy at an early age could be due to many causes, including exposure to diet drugs. Likewise, I have seen many patients who presented in their 60s and 70s with a bicuspid aortic valve and minimal aortic

stenosis. Therefore, no reasonable physician would rely on the patient's age. Instead, a reasonable physician would consider the physical evidence, which I detailed in my prior declaration. This evidence was not disputed by Dr. Wang.¹³

In response, the Trust argues that the Estate has not established a reasonable medical basis for Dr. Rosenthal's representation that Mr. Kennedy did not have a congenital aortic valve abnormality. In addition, the Trust asserts that it properly applied the reasonable medical basis standard. Finally, the Trust argues that the Estate improperly is seeking a determination contrary to the Court's previous holding that the Estate's aortic valve claim must be reduced to Matrix B.

The Technical Advisor, Dr. Vigilante, re-reviewed the echocardiograms dated February 7, 2002, March 5, 2007, and March 28, 2007, and concluded that there was no reasonable medical basis for Dr. Rosenthal's finding that Mr. Kennedy did not have a congenital bicuspid aortic valve. As to the February 7, 2002 echocardiogram, Dr. Vigilante stated, in pertinent part:

Without question, the aortic leaflets did not close in the mid line suggestive of a

13. The Estate also asserts that the Settlement Agreement and the Seventh Amendment to the Settlement Agreement "guaranteed class members certain benefits related to progression claims." We have rejected this argument. See, e.g., Mem. in Supp. of Separate PTO No. 9285 at 17 (June 3, 2014), aff'd, 601 F. App'x 143 (3d Cir. 2015).

bicuspid valve. Again, at time 2:59 on the tape, the parasternal short-axis view demonstrated a raphe and an obvious congenital bicuspid aortic valve. In addition, mild aortic regurgitation was seen on this study. Dr. Muttreja is wrong when he stated that the aortic leaflets closed in the mid line. An aortic insufficiency jet does not necessarily have to be eccentric when the leaflets do not close in the mid line. He is also wrong when he stated that, in real time, the aortic valve appeared to have three leaflets. Instead, it is clear that this is an obvious congenital bicuspid aortic valve when reviewing the real time images in the parasternal short-axis view. There is congenital fusion of the right and left coronary cusps. A raphe is present. Dr. Dlabal is also incorrect when he stated that the echocardiogram of February 7, 2002 demonstrated a trileaflet aortic valve. There is fusion of the right and left coronary leaflets.

As to the March 5, 2007 echocardiogram, Dr. Vigilante observed the following:

Once again, the leaflets do not close in the mid line of the valve noted in the parasternal long-axis view. In the parasternal short-axis view, there is obvious congenital fusion of the right and left coronary leaflets with a raphe diagnostic of a congenital bicuspid aortic valve. Dr. Muttreja is wrong when he stated that there was no evidence that the aortic valve did not close in the mid line. He is also inaccurate when he stated that there was no congenital fusion of the right and left coronary cusps of the aortic valve.

As to the March 28, 2007 echocardiogram, Dr. Vigilante observed, in relevant part:

This is an excellent quality study. Once again, there is obvious congenital fusion of

the left and right coronary leaflets resulting in a congenital bicuspid aortic valve with a raphe. This is noted in the real time loops 10, 11, 12, 13, 28, 29, 30, and 43. Dr. Muttreja is wrong when he stated that there was no congenital fusion of the right and left coronary leaflets. The time frames that Dr. Muttreja documented showing a supposed definite tricuspid aortic valve correlated to loops 12, 13, and 28. Without question, these three loops demonstrated a congenital bicuspid aortic valve. Dr. Dlabal is wrong when he stated that loops 28, 29, and 39 demonstrated three cusps and no congenital deformity. Instead, these three loops clearly demonstrate a congenital bicuspid aortic valve.

In response to the Technical Advisor Report, the Estate argues that the Technical Advisor "substituted his own non-objective erroneous opinions for all of the other evidence." According to the Estate, "there is absolutely no way that an objective cardiologist could form a clinical diagnosis of this condition."

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. At the outset, we previously rejected the Estate's arguments in PTO No. 9226 (Apr. 15, 2004). In affirming PTO No. 9226, our Court of Appeals ruled that:

The District Court properly relied on the specific findings of the auditing cardiologist and the Technical Advisor to dispose of the Estate's claim for Matrix A benefits. The auditing cardiologist stated that "a bicuspid aortic valve" was "clearly seen" on the March 28, 2007 echocardiogram. The Technical Advisor then explained in some

detail why the February 7, 2002, the March 5, 2007, and the March 28, 2007 echocardiograms indicated the existence of a congenital bicuspid aortic valve. In the process, he specifically addressed Dr. Dlabal's declaration and took into consideration the observations of the doctor who performed the aortic valve surgery. Given the record, we cannot conclude that the District Court committed an abuse of discretion in holding that the Estate failed to prove a reasonable medical basis for the attesting physician's finding regarding the absence of a congenital aortic valve abnormality.

In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine)

Prods. Liab. Litig., 601 F. App'x 162, 164-65 (3d Cir. 2015).

The issue presented in the Estate's current claim is the same as that addressed in PTO No. 9226. Accordingly, on this basis alone, the Estate is only entitled to Matrix B benefits for its Level V claim.

In any event, the Settlement Agreement requires the placement of the Estate's Level V claim on the B Matrix. In particular, a claim for Level V Matrix Benefits based on damage to the aortic valve must be reduced to the B Matrix if the Diet Drug Recipient had a congenital aortic valve abnormality, such as a bicuspid valve. See Settlement Agreement § IV.B.2.d.(2)(c)i)a). Although the Estate argues that there is a reasonable medical basis for finding Mr. Kennedy did not have a congenital aortic valve, the auditing cardiologist, Dr. Wang, reviewed Mr. Kennedy's March 28, 2007 echocardiogram and

determined that it demonstrated a congenital bicuspid aortic valve.¹⁴ In addition, Dr. Vigilante determined that Mr. Kennedy's February 7, 2002 echocardiogram, March 5, 2007 echocardiogram, and March 28, 2007 echocardiogram all revealed the presence of a congenital bicuspid aortic valve.

Dr. Vigilante also identified the specific deficiencies of the conclusions of the reviewing cardiologists, Dr. Muttreja and Dr. Dlabal.¹⁵

Finally, we reject the Estate's argument that the pathology report is "internally inconsistent" and cannot be used to establish that Mr. Kennedy had a congenital bicuspid aortic valve.¹⁶ To the contrary, the pathology report unequivocally

14. Dr. Wang's declaration and supplemental declaration also made clear that, contrary to the Estate's argument, Dr. Wang did not ignore Mr. Kennedy's operative report, his echocardiogram reports, or the results of his March 6, 2007 heart catheterization. Further, Dr. Wang did definitively conclude that Mr. Kennedy suffered from a "congenital" bicuspid aortic valve.

15. For these reasons as well, we reject the Estate's assertion that Dr. Vigilante merely "substituted his own non-objective erroneous opinions for all of the other evidence."

16. We also disagree with the Estate to the extent it argues that the Trust could only rely on an echocardiogram, a cardiac catheterization, or a surgical examination. Unlike other reduction factors, such as a rheumatic mitral valve, see Settlement Agreement § IV.B.2.d.(2)(c)ii)e), and mitral valve prolapse, see id. § I.39, the Settlement Agreement does not require that the presence of a congenital aortic valve abnormality be determined solely through echocardiographic evidence or surgical examination. As such, we will not interpret the Settlement Agreement so narrowly. In any event, the Estate
(continued...)

notes under the heading "Final Diagnosis" that Mr. Kennedy had a "[c]ongenitally bicuspid aortic valve with fibrosis."¹⁷

As the Estate has not established a reasonable medical basis for finding that Mr. Kennedy did not have a congenital bicuspid aortic valve, the Settlement Agreement requires that the Estate's Level V claim be reduced to the B Matrix. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A-1 benefits and the related derivative claim submitted by Mr. Kennedy's spouse.

16. (...continued)
ignores that Dr. Wang and Dr. Vigilante nevertheless determined that there was echocardiographic evidence of a congenital bicuspid aortic valve.

17. Although the Estate's additional reviewing cardiologist, Dr. Dlabal, asserts that Mr. Kennedy's aortic valve was "functionally" bicuspid, this assertion ignores the "Final Diagnosis" set forth in the pathology report, which specifically states that Mr. Kennedy's aortic valve was "congenitally" bicuspid.